IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

BOBBI VAN EMAN as personal representative of ROBERT VAN EMAN, Plaintiff,	)	
vs	)	Civil Action No. 11-792
NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	)	

REPORT AND RECOMMENDATION

REPORT

I. Introduction

Presently before the Court is Defendant's, Novartis Pharmaceuticals Corporation's ("NPC"), Motion for Summary Judgment. The sole issue for discussion is whether Plaintiff filed his claim within the statutory period. For the reasons that follow, it is respectfully recommended that Defendant's Motion for Summary Judgment be denied.

II. Background[1]

a. History of Bisphosphonate-Related Osteonecrosis of the Jaw ("BRONJ")

Aredia® and Zometa® are intravenous bisphosphonate medications used to prevent bone destruction that frequently occurs in cancer patients. Def.'s Statement of Material Facts [ECF No. 60] at ¶¶ 1-4.[2] Specifically, the medications "reduce the incidence of pathologic fractures

[1] Unless otherwise noted, the facts are undisputed by the parties.

[2] Zometa® remains distributed as an approved Food and Drug Administration ("FDA") medication, but it is

and spinal cord compression in patients whose cancers have spread to the bone." *Id*. at ¶ 4 (citing Ex. 6 [ECF No. 60-7] Coleman RE. *et al*., *Zoledronic Acid Use in Cancer Patients: More Than Just Supportive Care?* Cancer 117(1):11-23 (2011)). The clinical value of using bisphosphonates include extending the life of the patient, reducing skeletal complications, reducing pain, improving the quality of life for the patient and have potential to prevent the spread of cancer and increase the survival expectancy of the patient. Def.'s Statement of Material Facts [ECF No. 60] at ¶¶ 4-6.

Defendant Novartis Pharmaceutical Corporation ("NPC") is a pharmaceutical corporation that produces and distributes bisphosphonates such as Aredia® and Zometa®. Compl. [ECF No. 1] at ¶ 2. On September 26, 2003, NPC informed the FDA that it was revising the Zometa® labeling to include the following language in the Post-Marketing Experience section of the label:

> Cases of osteonecrosis[3] (primarily of the jaws) have been reported since market introduction. Osteonecrosis of the jaws has other well documented multiple risk factors. It is not possible to determine if these events are related to Zometa® or other bisphosphonates, to concomitant drugs or other therapies (e.g. chemotherapy, radiotherapy, corticosteroid), to patient's underlying disease, or to other co-morbid risk factors (e.g. anemia, infection, pre-existing oral disease).

Id. at ¶ 38 (citing Ex. 26 [ECF No. 60-27] 9/26/03 Sterner Letter to Orloff). In February 2004, NPC revised the Post-Marketing Experience of Zometa® label as follows:

> Cases of osteonecrosis (primarily involving the jaws) have been reported in patients treated with bisphosphonates. The majority of the reported cases are in cancer patients attendant to a dental procedure. Osteonecrosis of the jaws has multiple well documented risk factors including a diagnosis of cancer, concomitant therapies (e.g. chemotherapy, radiotherapy,

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unclear from the record whether Aredia® is still distributed. Zometa® is approved by the FDA for the treatment of patients with hypercalcemia of malignancy, multiple myeloma and bone metastases from solid tumors. Def.'s Statement of Material Facts [ECF No. 60] at ¶ 1.

[3] Osteonecrosis means "bone death." *See* Compl. [ECF No. 1] at ¶ 12.

> corticosteroids) and co-morbid conditions (e.g. anemia, coagulopathies, infection, pre-existing oral disease). Although causality cannot be determined, it is prudent to avoid dental surgery as recovery may be prolonged.

Id. at ¶ 40 (citing Ex. 28 [ECF No. 60-29] 2/27/04 Pazdur Letter to Miranda).

In September 2004, NPC revised the Zometa® label to include the following language in the "Precautions" section of the label, and distributed letters to oncologists and oral surgeons reflecting the same:

> Osteonecrosis of the jaw (ONJ) has been reported in patients with cancer receiving treatment regimens including bisphosphonates. Many of these patients were also receiving chemotherapy and corticosteroids. The majority of reported cases have been associated with dental procedures such as tooth extraction. Many had signs of local infection including osteomyelitis.
>
> A dental examination with appropriate preventative dentistry should be considered prior to treatment with bisphosphonates in patients with concomitant risk factors (e.g., cancer, chemotherapy, corticosteroids, poor oral hygiene).
>
> While on treatment, these patients should avoid invasive dental procedures if possible. For patients who develop ONJ while on bisphosphonate therapy, dental surgery may exacerbate the condition. For patients requiring dental procedures, there are no data available to suggest whether discontinuation of bisphosphonate treatment reduces the risk of ONJ. Clinical judgment of the treating physician should guide the management plan of each patient based on individual benefit/risk assessment.

Id. at ¶¶ 41-43. In May, 2005, NPC sent a mass-mailing letter to dentists informing the recipients of the language change concerning BRONJ in the Zometa® label. It read:

> The prescribing information recommends that cancer patients:
>
> - receive a dental examination prior to intitiating therapy with intravenous bisphosphonates (Aredia® and Zometa®); and
>
> - avoid invasive dental procedures while receiving bisphosphonate treatment. For patients who develop ONJ while on bisphosphonate therapy, dental surgery may

> exacerbate the condition. Clinical judgment by the treating physician should guide the management plan of each patient based on individual benefit/risk assessment.

Id. at ¶¶ 46-47 (citing Ex. 32 [ECF No. 60-33] 5/5/05 Dear Dentist Letter).

In 2006, the American Association of Oral and Maxillofacial Surgeons issued guidelines regarding bisphosphonate-related osteonecrosis of the jaws ("BRONJ") that stated the following:

> Patients may be considered to have BRONJ (Bisphosphonate-Related Osteonecrosis of the Jaw) if all of the following three characteristics are present:
>
> (1) Current or previous treatment with a bisphosphonate;
>
> (2) Exposed bone in the maxillofacial region that has persisted for more than eight weeks; and
>
> (3) No history of radiation therapy to the jaws.

Id. at ¶ 18 (citing Exhibit 18 [ECF No. 60-19] AAOMS "Position Paper on Bisphosphonate-Related Osteonecrosis of the Jaws" (2006) at 2).

In September 2007, Defendant changed the formatting of the Zometa® package insert and relocated three paragraphs about BRONJ that had previously been in the "Precautions" section into a separate sub-heading labeled "**5.4 Osteonecrosis of the Jaw**" and also addressed BRONJ in the "Adverse Reactions" section under "Postmarketing Experience" and labeled it under its own separate sub-hearing entitled "Osteonecrosis of the Jaw." *Id*. at ¶¶ 48-49 (citing Ex. 33 [ECF No. 60-34] 2007 Zometa® Label).

2. Plaintiff's Medical History

Robert Van Eman[4] ("Plaintiff") was diagnosed with multiple myeloma on or about December 4, 1997. "Multiple myeloma is an incurable, systemic cancer of the plasma cells that

[4] Mr. Van Eman passed away on March 30, 2013 after commencement of this action. His daughter and representative of the estate, Bobbi Van Eman was substituted as plaintiff on May 8, 2013. *See* Order of 5/8/2013 [ECF No. 55]. However, for clarity purposes, "Plaintiff" refers to Mr. Van Eman.

attacks the skeleton, resulting in bone destruction." Def.'s Br. in Supp. of Mot. for Summary Judgment [ECF No. 59] at 3. Aredia® was prescribed to Plaintiff on or about June 11, 1998 by his oncologist, Dr. Dennis Brunskill, after he suffered multiple spine fractures as a consequence of the multiple myeloma. Def.'s Statement of Material Facts [ECF No. 60] at ¶¶ 8-9, 12. On or about November 20, 2001, Dr. Brunskill replaced the Aredia® with Zometa® because it was more effective and had a shorter infusion time for patients. *Id*. at ¶¶ 14-16. Plaintiff remained on Zometa® until July 14, 2009. *Id*. at ¶ 17.

On April 26, 2007, Plaintiff first visited dentist Daniel P. Hasley, DMD because he was experiencing problems with two of his teeth, a first upper right molar ("tooth three)" and a second upper right molar ("tooth two"). Def.'s Statement of Material Facts [ECF No. 60] at ¶ 19; Hasley Dep. [ECF No. 62-2] at 94-96, 103; *See also* Pl.'s Concise Statement of Material Fact Ex. B [ECF No. 62.3] Diagram of the Tooth Numbering System (graphic labeling teeth by number). According to Dr. Hasley, Plaintiff's teeth were "decayed beyond the point where they could not be restored with a root canal or any crown or any conventional way, so the only option for treatment at that point [was] removal[.]" Hasley Dep. [ECF No. 62-2] at 96. On that same day, tooth three was extracted. Def.'s Statement of Material Facts [ECF No. 60] at ¶ 19. On May 19, 2007, Dr. Hasley extracted tooth two. *Id*. at ¶ 20. Approximately a month later, after the first two extractions, on June 14, 2007, Plaintiff visited Dr. Hasley again for a post-extraction appointment. *Id*. at ¶ 24. Dr. Hasley noted that "patient presents with incomplete healing on upper right ride of [mouth]. Still has bone exposure. May be due to multiple myeloma[.]" *Id*. at ¶ 24 (citing Ex. 23 [ECF No. 60-24] 6/14/07 Health Care Record; Hasley Dep. [ECF No. 62-2] at 104.

Plaintiff next presented to Dr. Hasley on August 8, 2007, because of pain in his upper

right bicuspid ("tooth five"). Def.'s Statement of Material Facts [ECF No. 60] at ¶ 22; Hasley Dep. [ECF No. 62-2] at 110-111. Dr. Hasley testified that tooth five was decayed, although not to the extent of tooth two or three and a root canal could have been a treatment option to save tooth five. Hasley Dep. [ECF No. 62-2] at 111-112. However, tooth five was extracted the same day. Def.'s Statement of Material Facts [ECF No. 60] at ¶ 22 (citing Ex. No. 22 [ECF No. 60-23] 8/8/2007 Health Care Record). Dr. Hasley opined that the cost to extract the tooth was less than the cost for a root canal and this supported Plaintiff's decision to extract the tooth rather than have a root canal performed. Hasley Dep. [ECF No. 62-2] at 112.

On January 29, 2008, Plaintiff again presented to Dr. Hasley's office complaining of pain in his right eye tooth ("tooth six"). *Id*. at 114-115. As to tooth six, Dr. Hasley testified:

> A: [I]t had mobility, which means – what I think we're seeing here was the bone really deteriorating in his jaw either from [BRONJ] or from the multiple myeloma. We don't know at this point.
>
> Q: Although the first three teeth were decayed, correct?
>
> A: Right.
>
> Q: That's the actual tooth decay, not the bone?
>
> A: That's correct.
>
> Q: What about [tooth] number 6, was that tooth decayed?
>
> A: That tooth was not decayed, but that tooth was mobile.
>
> Q: Which means it can move?
>
> A: Yes. When teeth are mobile, generally that indicates the presence of gum disease or some other factor.

Id. at 115. Dr. Hasley determined that tooth six needed to be extracted, and put Plaintiff on antibiotics and scheduled to have the tooth extracted the next week. *Id*. at 116.

On January 29, 2008[5], Plaintiff visited his oncologist Dr. Brunskill to complete blood work. Def.'s Statement of Material Facts Ex. 24 [ECF No. 60-25] 1/31/08 Health Care Record. Dr. Brunskill noted the following on Plaintiff's patient record:

> [Plaintiff] has had a couple of teeth pulled and does have bone exposed in the upper jaw on the right side. . . . Apparently there's another tooth that might be abscessed and Dr. Hasley is going to pull that. I'll need to contact Dr. Hasley and let him know that [Plaintiff] is on Zometa®. I explained to [Plaintiff] about the potential for osteonecrosis of the jaw.

Id. As to this appointment, Dr. Brunskill testified:

> Q: [W]hen he presented to you on January 29, 2008, it says here he had bone exposed in his upper jaw on the right.
>
> A: Right.
>
> Q: You didn't diagnose him with osteonecrosis of the jaw on that day?
>
> A: Not at that time, because it was not clear. There was no - - as I remember, there [w]as no necrotic bone. . . . It looked like . . . if you have a tooth pulled and you're looking at the socket . . . it looked like that. There was no pus. I don't remember whether there was any surrounding erythema or redness, but . . . we were concerned about the possibility, but I didn't feel that we could make the diagnosis at that time.
>
> . . .
>
> Q: . . . Regardless of that, you continued Mr. Van Eman on his Zometa® therapy?
>
> A: Yes.
>
> Q: Did you consider stopping Zometa® therapy at that point?
>
> A: We considered it, but there were two things that came into

[5] It is unclear from the record whether this appointment took place on January 29, 2008, or January 31, 2008. Dr. Brunskill's records indicate that Plaintiff was seen on January 29, 2008, while he testified that the appointment took place on January 31, 2008. This discrepancy is not material to the disposition of this matter; therefore the Court will adopt the date noted on the patient record. *Compare* Def.'s Statement of Material Facts Ex. 24 [ECF No. 60-25] 1/31/08 Health Care Record *with* Brunskill Dep. [ECF No. 62-5] at 204-205.

> consideration: One was we were unsure that this is what it was - - well, actually more than two things. The second thing was, well, we're starting to run out of therapies here to use on [Plaintiff], and thirdly, as far as I could tell from reviewing what literature I had, there was a question whether stopping or continuing was of benefit or not anyway in terms of what you should do in this kind of a situation.
>
> So based on the fact that his disease was probably progressing as far as we could tell, we decided to continue the lower-dose Zometa® that he had been on and to continue putting him back on Alkeran in hopes that we'd get a response.

Brunskill Dep. [ECF No. 62-5] at 204-06.

That same day, Dr. Brunskill noted: "I spoke to Dr. Hasley about [Plaintiff]. Dr. Hasley is aware of the possibility of osteonecrosis of the jaw and he said the panorex[6] looked fine and didn't see anything that looked bad jawbone wise." *Id.* As to this conversation, Dr. Brunskill testified:

> Apparently, [Dr. Hasley] thought [Plaintiff] has an abscess in the area. . . . I did speak to Dr. Hasley myself. We were concerned about the possibility of osteonecrosis in the jaw at that point. I spoke to Dr. Hasley. He was aware of the risks for osteonecrosis of the jaw.

Id. at 195-96 (emphasis added). Dr. Brunskill further testified:

> Q: … And you indicated after that: I'll need to contact Dr. Hasley to let him know that Bob is on Zometa®.
>
> A: Right.
>
> Q: Why did you need to –
>
> A: That was – well, I mean, because we were aware of it. Any type of surgical intervention . . . in these people who are on Zometa® or bisphosphonates increases the risk for the development of osteonecrosis of the jaw, okay, and we were concerned that if he had an abscess, that the doctor be aware of what we were doing, that he was on Zometa®, that there was a risk for osteonecrosis of the jaw, okay, and that he take every precaution to have, you know, as atraumatic an approach as he

[6] A panorex is a "full mouth x-ray." *See* Hasley Dep. [ECF No. 62-2] at 64.

could[.] . . .

Id. at 196-98.

Plaintiff presented to Dr. Hasley on February 5, 2008 during which appointment, tooth six was extracted and Dr. Hasley reported mobility of Plaintiff's lateral incisor ("tooth seven"). Hasley Dep. [ECF No. 62-2] at 121-122. There is no record of Plaintiff receiving any dental treatment between February 5, 2008 and May 7, 2009. Def.'s Statement of Material Fact [ECF No. 60] at ¶ 35. During the May 7, 2009 appointment with Dr. Hasley, Plaintiff's upper left first bicuspid was extracted ("tooth number 12"). Hasley Dep. [ECF No. 62-2] at 123.

On July 28, 2009, Plaintiff presented to Dr. Brunskill's office and complained of problems with his teeth. Dr. Brunskill testified:

> So this time we looked at it and there clearly was exposed bone, and as I recall, . . . I was again really concerned that we're dealing with osteonecrosis of the jaw here.
> . . .
> [T]he review of the literature had really shown that once a patient develops osteonecrosis of the jaw, your therapeutic options are extremely limited. . . . Basically, it is symptomatic therapy to give antibiotics to reduce any infection, to give something like Peridex to reduce the organisms in the mouth, to avoid any major surgical approaches to this thing, because, generally that makes things worse. . . . We decided that we would stop the Zometa® [.] . . . We talked about exposed bone. . . . We did consult with an oral surgeon, Dr. Paladino, who agreed that this was osteonecrosis of the jaw at the time.

Brunskill Dep. [ECF No. 62-5] at 214-15. Dr. Brunskill further testified:

> Q: [I]n January of 2008, you had a discussion with Mr. Van Eman . . . concerning precautions he should take in terms of having any kind of dental work done while he was on Zometa® therapy?
>
> A: Yes.
>
> Q: When you had this discussion with him again in July of 2009, did he seem to have recalled that?

> A: Not that I remember.
>
> Q: . . . Was your impression that in July of 2009 when you told him this again, that he did not recall the prior discussion?
>
> A: That was my impression.
>
> Q: But if your notes reflect that you told him about the potential risk in January of '08, you have no doubt that you actually had that discussion with him. . . .
>
> A: I don't have a doubt that I ultimately had that discussion with him . . . and I was surprised when he came in and said he's got a problem again.

Id. at 216-17.

On September 1, 2009, Plaintiff again presented to Dr. Hasley's office for problems with his gums. Hasley Dep. [ECF No. 62-2] at 125. Dr. Hasley referred Plaintiff to an oral surgeon and noted "Patient will need to see an oral surgeon because of his medications." *Id*. at 126. Dr. Hasley testified that "medications" probably indicated bisphosphonates, but he did not "have a specific recollection" as to this point. *Id*. at 126. When asked whether he actually diagnosed Plaintiff with BRONJ, Dr. Hasley testified: "What I did was I referred him to an oral surgeon. I believe I wanted - - you know what, I didn't document this, but I believe - - when I saw that he did not heal from those extractions, I believe I sent him over there in '07, but I don't believe he went there till '09." *Id*. at 70. On October 1, 2009, Plaintiff was definitively diagnosed with BRONJ by Dr. Sarah Davies, an oral maxillofacial surgeon. Def.'s Statement of Material Fact [ECF No. 60] at ¶ 37.

Plaintiff filed the instant action on April 14, 2011, alleging (1) strict liability; (2) negligent manufacturing; (3) negligence for a failure to warn; (4) breach of express warranty; and (5) breach of implied warranty.[7] Compl. [ECF No. 1] at 9-14. NPC moved for summary

[7] Plaintiff initially filed his complaint in the United States District Court for the Central District of

judgment arguing that Plaintiff's claims are timed-barred because the cause of action accrued over three years before Plaintiff filed suit. *See* Def.'s Br. in Supp. of Mot. for Summary Judgment [ECF No. 59] at 1. Specifically, NPC argues that "[a]s early as June 2007, [Plaintiff] had symptoms diagnostic for [BRONJ] - - exposed bone in his mouth from non-healing tooth extractions - - and in January 2008 [Dr. Brunskill] told him that he potentially had [BRONJ] from Aredia® and Zometa®." *Id.* at 1-2. Moreover, NPC argues that Pennsylvania's discovery rule does not save Plaintiff's claims from being time barred because he knew of his actual injury and its potential cause over three years before the complaint was filed, or alternatively, he did not exercise reasonable diligence in investigating the cause of his jaw injury after learning that Aredia® and Zometa® potentially caused his injury. *Id.* at 2. Plaintiff argues that because he "was not diagnosed with [BRONJ] until October [1], 2009, his claim is timely. [Alternatively, e]ven if the earliest possible date when his symptoms first arose is utilized (*i.e.*, between the May 7, 2009 appointment with Dr. Hasley and the July 28, 2009 appointment with Dr. Brunskill), the complaint is still within the two-year statute of limitations" because he did not "suffer an objective and ascertainable injury until at or around the time of his appointment with Dr. Brunskill on July 28, 2009." Pl.'s Br. in Op. to Def.'s Mot. for Summary Judgment [ECF No. 61] at 9, 11.

California. Pursuant to 28 U.S.C. § 1404(a), the case was transferred to this Court. See Minute Entry of 6/14/2011 [ECF No. 13]. As the transferor forum, California choice-of-law rules govern to Plaintiff's claim. *Ferens v. John Deere Co.*, 484 U.S. 516, 523 (1990) (transferor's choice-of-law rules apply where case is transferred pursuant to 28 U.S.C. § 1404). Under California's borrowing statute, where a resident of another state attempts to apply California law to commence an action barred in the jurisdiction in which the claims arose, California law applies the foreign jurisdiction's statute of limitations. *See* Cal. Civ. Proc. Code § 361 ("When a cause of action has arisen in another State, or in a foreign country, and by the laws thereof an action thereon cannot there be maintained against a person by reason of the lapse of time, an action thereon shall not be maintained against him in this State, except in favor of one who has been a citizen of this State, and who has held the cause of action from the time it accrued."); *Dalkilic v. Titan Corp.*, 516 F.Supp.2d 1177, 1184 (S.D.Cal. 2007) ("California's borrowing statute discourages forum shopping by foreign plaintiffs by 'borrowing' the statute of limitations from the state in which the cause of action arose."). In the instant case, Plaintiff at all relevant times was a citizen of Pennsylvania. He was treated with Aredia® and Zometa® and developed BRONJ in Pennsylvania. Plaintiff was never a California resident and his substantive claims arose in Pennsylvania, therefore Pennsylvania's two year statute of limitations applies. *See* 42 Pa.C.S.A.§§ 5524(2), (7).

III. Jurisdiction

Jurisdiction is proper under 28 U.S.C. § 1332, as the amount in controversy exceeds the jurisdictional amount and diversity exists between the parties, as Plaintiff is a citizen of Pennsylvania and Defendant is a Delaware corporation with its corporate headquarters located in New Jersey. *See* Compl. [ECF No. 1] at 2-4.

IV. Standard of Review

Under Federal Rule of Civil Procedure 56, summary judgment is appropriate if "there is no genuine issue as to any material fact and . . . the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). A moving party is entitled to summary judgment if he demonstrates that "the nonmoving party has failed to make a sufficient showing of an essential element of [his] case." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The nonmoving party bears the burden of adducing palpable evidence "establishing that there is a genuine factual dispute for trial" and may not merely rely upon "bare assertions or conclusory allegations" to survive summary judgment. *Hogan v. Twp. of Haddon*, 278 Fed.App'x 98, 101 (3d Cir. 2008) (citing *Fireman's Ins. Co. v. DuFresne*, 676 F.2d 965, 969 (3d Cir. 1982)). "A motion for summary judgment will not be defeated by 'the mere existence' of some disputed facts, but will be denied [only] when there is a genuine issue of material fact." *Am. Eagle Outfitters v. Lyle & Scott Ltd.*, 584 F.3d 575, 581 (3d Cir. 2009) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986) ("there is no genuine issue if the evidence presented in the opposing affidavits is of insufficient caliber or quantity to allow a rational finder of fact to find [for Plaintiffs] by clear and convincing evidence")).

V. Analysis

In diversity actions, "[a] federal court applies the substantive law of its forum state[.]"

Danysh v. Eli Lilly and Co., 2011 WL 4344601, at *6 (M.D.Pa. 2011) (citing *Lafferty v. St. Piel*, 495 F.3d 72, 76 (3d Cir. 2007)). Here, Plaintiff's claims are governed by a two-year statute of limitations. *See* 42 Pa. Cons. Stat. § 5542(2) (2004) (two year statute of limitations period for personal injury claims). The Pennsylvania Supreme Court has explained the law regarding its statute of limitations rules for personal injury actions:

> The Judicial Code provides in pertinent part that limitations period are computed from the time the cause of action accrued. In Pennsylvania, a cause of action accrues when the plaintiff could have first maintained the action to a successful conclusion. Thus, [Pennsylvania has] stated that the statute of limitations begins to run as soon as the right to institute and maintain a suit arises. Generally speaking, in a suit to recover damages for personal injuries, this right arises when the injury is inflicted. Mistake, misunderstanding, or lack of knowledge in themselves do not toll the running of the statute. Once a cause of action has accrued and the prescribed statutory period has run, an injured party is barred from bringing his cause of action.

Fine v. Checcio, 870 A.2d 850, 857 (Pa. 2005) (citations omitted). That the plaintiff must maintain the action to a successful conclusion does not mean that the "plaintiff must be able to prevail on the merits, but that an injury has occurred, a right of recovery has arisen, and thus the injured party can survive a motion to dismiss for failure to state a claim." *Danysh*, 2011 WL 4344601, at *9.

Where the plaintiff's injury is neither known nor reasonably knowable, he can invoke the discovery rule to toll the statute of limitations. *See generally Fine*, 870 A.2d at 858. The purpose of the discovery rule is to permit a plaintiff who "has not suffered an immediately ascertainable injury . . . the same rights as those who have suffered . . . an [immediately ascertainable] injury." *Id*. The statute of limitation period "commences when the plaintiff learns that [he] has an injury and its cause." *Wilson v. El Daief*, 964 A.2d 354, 359 (Pa. 2009). Thus, the "salient point giving rise to its application is the inability of the injured, despite the exercise of reasonable diligence,

to know that he is injured and by what cause." *Fine*, 870 A.2d at 858. A party seeking to invoke the discovery rule has the burden of proof to show he exercised reasonable diligence to discover his injury and its cause. *Wilson*, 964 A.2d at 363 (citations omitted).

In cases involving latent injuries, or "injuries of unknown etiology," *Id*. at 356 "Pennsylvania common law . . . recognizes the discovery rule, which tolls the statute of limitations until a plaintiff actually discovers the harm caused by an earlier inflicted but latent injury." *Lake v. Arnold*, 232 F.3d 360, 367 (3d Cir. 2000). In a latent disease case, the statutory time period "begins to run . . . at the moment at which the plaintiffs possessed 'sufficient critical facts to put [them] on notice that a wrong has been committed and that [they] need to investigate to determine whether [they were] entitled to redress.'" *Debiec v. Cabot Corp*., 352 F.3d 117, 130 (3d Cir. 2003) (quoting *Zeleznik v. United States*, 770 F.2d 20, 23 (3d Cir. 1985)). Nevertheless, that a plaintiff knows he has been injured in some way

> is not sufficient to trigger such inquiry. One must have some reason to suspect that the injury was caused by a third party to impose a duty to investigate further. Where the injury is one that may result from nontortious conduct, such as a disease, that point may be difficult to discern without resolving factual issues. Subjective differences among persons and the situations in which they find themselves are relevant in making that determination.

Coleman v. Wyeth Pharmaceuticals, Inc., 6 A.3d 502, 510-11 (Pa. Super. Ct. 2010). A plaintiff's cognizance of an injury and its cause is a fact-intensive process and Pennsylvania courts have determined that this issue is "best determined by the collective judgment, wisdom and experience of jurors." *Id*. at 510 (citations omitted).

For example, in *Wilson*, the plaintiff brought a medical malpractice action in October 2003 against her surgeon for negligently lacerating the radial nerve in her wrist during one of two surgeries in May or August 2000. *Wilson*, 964 A.2d at 356. After the second surgery, she

experienced "constant, persistent, excruciating pain; within several weeks, her hand contracted into a fist, her right elbow bent inward, and her right shoulder drew upward." *Id*. The Superior Court found that the cause of action arose in August 2000, the date of the second surgery, and that plaintiff was barred by the statute of limitations for not filing suit within two years. *Id*. Plaintiff appealed, arguing, *inter alia*, the discovery rule applied and that the "court failed to explain how a person with no medical education would be expected to know that the source of her pain and contractures was a surgical injury to a sensory nerve when a competent orthopedic surgeon consulting with the defendant . . . had only a four part differential diagnosis[,]" and the surgeon himself testified that the lacerated nerve could have been caused by a factor other than the alleged negligent surgery, and he failed to diagnose the laceration because her symptoms were not suggestive of a severed radial nerve. *Id*. at 360. The Pennsylvania Supreme Court reversed the Superior Court and found that factual issues were present pertaining to plaintiff's notice and diligence of her injury, and should have been decided by a jury. *Id*. at 366. In finding so, the high Court stated:

> [Defendants'] perspective is that injury is reflected in symptoms – [plaintiff's] severe pain and physical clubbing and contraction – and cause in the close temporal relationship between the symptoms and the surgery. [Plaintiff's] view, on the other hand, is that "injury should mean the lacerated nerve, or if the pain and physical symptoms are enough to provide notice of the injury in the abstract, knowledge of the "cause" should encompass at least an appreciation that the nerve was lacerated, if not an understanding of the alleged negligent act. . . . [Plaintiff] believes that discovery of her underlying medical condition, or the nature of her condition, was necessary to trigger the commencement of the limitations period, so long as her conduct in pursuing such medical explanation may be regarded as reasonably diligent, and particularly in the light of the professionals' inability to provide any explanation to her throughout the default period of limitations.

Id. at 365.

Here, NPC argues that Plaintiff developed "exposed jaw bone" in June 2007 and this constituted an injury because Plaintiff experienced the symptoms of BRONJ, specifically, exposed bone in the jaw for more than eight weeks in a patient taking a bisphosphonate like Aredia® or Zometa®. *See* Def.'s Br. in Supp. of Mot. for Summary Judgment [ECF No. 59] at 10. Thus, because Plaintiff met the diagnosis in 2007, this constitutes a "physically objective and ascertainable injury." *Id*. Moreover, NPC argues that in January 2008, Plaintiff had actual knowledge of the cause of his injury after Dr. Brunskill conveyed that the exposed bone was potentially BRONJ and related to Plaintiff's Aredia® and Zometa® use. *Id*. NPC argues that Plaintiff cannot invoke the discovery rule because he was aware of his injury and its cause by January 2008 at the latest and this tolled the limitations period. Specifically, Plaintiff knew of the exposed bone in his upper right jaw following non-healing extractions while being treated with Zometa®. NPC finally argues that the non-diagnosis of BRONJ is irrelevant because "awareness of the injury and suspicion of its cause are enough to begin the running of the limitations period." *Id*. at 11 (quoting *Danysh*, 2011 WL 4344601, at *8).

The Court finds that there are material factual disputes as to when Plaintiff actually developed BRONJ, and whether Plaintiff's injury was known or reasonably knowable to him to toll the statute of limitations. Reasonable minds could differ as to when Plaintiff sustained his injury and whether he exercised reasonable diligence in pursuing a medical explanation. *See Seitzinger v. American Red Cross*, 1991 WL 88023, at *7 (E.D.Pa. 1991) (material factual disputes present in determining the tolling of the limitations period where plaintiff had been infected with HIV but did not know of his AIDS diagnosis). It is undisputed that Plaintiff was diagnosed with BRONJ on October 1, 2009, however, it is disputed as to when Plaintiff suffered his injury by first developing BRONJ. There are factual disputes as to whether Plaintiff's initial

symptoms were actually BRONJ or a result of his multiple myeloma. While NPC would have the Court believe that Plaintiff developed BRONJ after he first experienced symptoms common to BRONJ in June 2007 when Dr. Hasley noted in his dental records: "incomplete healing on upper right side of mouth. Still bone exposure[,]" both Dr. Hasley and Dr. Brunskill testified that while they were concerned with Plaintiff developing BRONJ throughout his treatment, they did not believe that BRONJ was present at that time. While NPC is correct in its assertion that a diagnosis is not necessary to begin the limitations period, *see Danysh*, 2011 WL 4244601, at *8 (citing *Gleason v. Borough of Moosic*, 15 A.3d 479, 485 (Pa. 2011)), there is a factual dispute as to when Plaintiff developed BRONJ so as to trigger the statute of limitations period.

Additionally, in January 2008, when Dr. Brunskill noted that Plaintiff had bone exposed in his upper jaw on the right side, he explained to Plaintiff the "potential" for osteonecrosis. What Dr. Brunskill suggested by this statement in context of when Plaintiff developed osteonecrosis or whether Plaintiff should have discovered his injury is an issue of material fact for a jury to determine. On that same date, Dr. Brunskill and Dr. Hasley had converging analyses of Plaintiff's condition and determined that he did not have BRONJ at that time. Dr. Brunskill testified that he did not see any necrotic bone, and as such, did not diagnose him with BRONJ. Dr. Brunskill noted that Dr. Hasley stated that the panorex "looked fine" and did not indicate any jawbone issues. While Dr. Hasley and Dr. Brunskill contemplated that BRONJ was a medical issue that could develop after Plaintiff underwent the dental procedures, they were both reluctant to make such a determination until 2009. It is reasonable that Plaintiff's injury could have occurred the first time he had teeth extracted, after subsequent extractions, or not until after July 28, 2009 appointment with Dr. Brunskill when he noted "clearly exposed bone." There are material factual disputes as to when Plaintiff knew he suffered from BRONJ and

whether Plaintiff exercised reasonable diligence in determining his injury.

Moreover, the analysis in *Wilson* is instructive to the instant case. NPC argues that Plaintiff's symptoms (*i.e.*, the tooth extractions and the non-healing bone) triggered the injury and because Dr. Brunskill told Plaintiff about the link between Zometa® and BRONJ, Plaintiff had knowledge of his injury in January 2008. However, there are material factual disputes as to whether Plaintiff exercised reasonable diligence to discover his injury and its cause. He was not diagnosed with BRONJ prior to October 2009, and his dentist and oncologist told him of the "possibility" of BRONJ and testified that they did not witness symptoms indicative of BRONJ in January 2008. Whether Plaintiff contracted BRONJ at some time prior to his diagnosis is a factual determination for the jury. As a result, because there are issues of material fact regarding when Plaintiff developed BRONJ and if he developed BRONJ prior to April 14, 2009, whether he exercised reasonable diligence in determining his injury and its cause, these issues must necessarily be determined by a jury.

VI. Conclusion

Because there are material factual disputes for which reasonable minds could differ, it is respectfully recommended that Defendant's, Novartis Pharmaceutical Corporation's, Motion for Summary Judgment [ECF No. 58] be denied.

RECOMMENDATION

For the aforementioned reasons, it is respectfully recommended that Defendant's Motion for Summary Judgment [ECF No. 58] be denied. Parties seeking to challenge this Report and Recommendation must seek review by the district judge by filing objections within fourteen (14) days of this date. Failure to do so will waive the right to appeal. Any party opposing written objections shall have fourteen (14) days from the date of service of the objections to respond thereto.

Dated: September 10, 2013

Respectfully submitted,

/s Robert C. Mitchell
Robert C. Mitchell
United States Magistrate Judge